

# **ETHICS OF ENGINEERING EDUCATION**

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## VACCINE MANUFACTURING IN ISLAMIC PERSPECTIVE

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### ABSTRACT

Recent progress in biotechnology and basic immunology is leading to the development of a wide range of new vaccines raising possibilities for the prevention of infectious diseases. In addition, improvement to already licensed vaccine is also being considered leading to new products as well as the introduction of a new type of adjuvant. However, the complexity and novelty of these products presents scientific and regulatory challenges, as criteria for their safety, potency and quality assessment may not always exist. Another important challenge being debated is of the production of halal vaccine that can be used by Muslims all over the world, which must come from allowable or permitted sources. The guiding principle of Good Manufacturing Practice (GMP) is that quality is built into a product, and not just tested. Therefore, the assurance is that the product not only meets the final specifications, but that it has been made by the same procedures under the same conditions each and every time it is made. Islamic validation is the part of GMP that ensures the facility systems, equipments processes and test procedures are in control and therefore consistently produce a quality vaccine product. Therefore in this paper the halal of biological manufacturing will be highlighted by discussing the good manufacturing processes and validation regulations of the vaccine

*Keywords: vaccine, biomanufacturing, halal*

### 1. INTRODUCTION

The concept of vaccination is to stimulate or induce the body's defense system to recognize and keep into memory the foreign particle that is being introduced into it so that at any point in time it encounters that foreign particle, It can destroy it without causing any harm to the organism's body, thus being protected against the deleterious effects of that particle. Islam does not intend to put forth a new method of manufacturing vaccines rather; it tries to sanitize the processes involved (from materials used in the process, environment developed for the process, personnel involved in the process, propagation of the antigenic particle, harvesting, purification, up scaling, storage, labeling, packaging) so that the whole of humanity can live freely without being selective of what they have to use, thus, relief of doubts. The Islamic Empire for more than 1000 years remained the most advanced and civilized nation in the world. This is because Islam stressed the importance and respect learning, forbade destruction, developed in Muslims the respect for authority and discipline (Haddad, 1942), and tolerance for other religions (Minkin, 1968). The Muslims recognized excellence and hungering intellectually were avid for the wisdom of the world of Galen, Hippocrates, Rufus of Ephesus, Oribasius, Discorides and Paul of Aegina. By the tenth century their zeal and enthusiasm for learning resulted in all essential Greek medical writings being translated into Arabic in Damascus, Cairo, and Baghdad. The Muslims became scientific innovators with originality and productivity. Islamic medicine is one of the most famous and best known facets of Islamic civilization, and in which the Muslims most excelled. The Muslims were the great torchbearers of international scientific research (Syed, 2008).

The most brilliant contribution was made by Al-Razi who differentiated between smallpox and measles, two diseases that were hitherto thought to be one single disease. He is credited with many contributions, which include being the first to describe true distillation, glass retorts and luting,

corrosive sublimate, arsenic, copper sulfate, iron sulphate, saltpeter, and borax in the treatment of disease. He introduced mercury compounds as purgatives (after testing them on monkeys); mercurial ointments and lead ointment." Pharmacology took roots in Islam during the 9<sup>th</sup> century. Yuhanna bin Masawayh (777-857 A.D.) started scientific and systematic applications of therapeutics at the Abbasids capital. His students Hunayn bin Ishaq al-Ibadi (809-874 A.D.) and his associates established solid foundations of Arabic medicine and therapeutics in the ninth century. In his book *al-Masail* Hunayn outlined methods for confirming the pharmacological effectiveness of drugs by experimenting with them on humans. He also explained the importance of prognosis and diagnosis of diseases for better and more effective treatment. Methods of extracting and preparing medicines were brought to a high art, and their techniques of distillation, crystallization, solution, sublimation, reduction and calcinations became the essential processes of pharmacy and chemistry. With the help of these techniques, the Saydalanis (pharmacists) introduced new drugs such as camphor, senna, sandalwood, rhubarb, musk, myrrh, cassia, tamarind, nutmeg, alum, aloes, cloves, coconut, nuxvomica, cubebs, aconite, ambergris and mercury (Syed, 2008).

## 2. ISLAMIC VIEWS ON THERAPEUTICS

Islam is a way of life to live, a system to be followed, a code of ethics and a constitution to be applied in the daily life of every person. As such, Islam has many constructive ideas to offer in the fields of health and medicine. In order to find out what Islam teaches, one has to read the Qur'an and the Hadith. Allah says in the Qur'an (Ash-Shu'ara') about healing from diseases:

"..... and when I sicken, then He (Allah) heals me (QS 26:80)."

As far as the Prophet is concerned, related to the healing of diseases, it was reported by Jabir bin Abdullah that Prophet Muhammad (pbuh) said:

"For any disease there is a cure, and when the cure matches the disease, the person recovers by the will of Allah ....."

The prophet also said about the healing of diseases:

It was reported by Abu Hurairah that the Prophet (pbuh) said:

"Allah never inflicts a disease unless he makes a cure for it. ..."

As far as the treatment of diseases, it was reported by Usamah bin Shareek saying:

"I was with the Prophet (pbuh) and Arabs came to him asking: 'O messenger of Allah: Do we take medicine for treatment?' He said: 'Yes, Oh you the servants of Allah, take medicine, as Allah almighty has not created a disease without having created a cure for it except one disease.' They asked, 'What it is?' He said: 'Old age.'" In another saying: "Allah never inflicts a disease without providing a cure; only those who were aware of it knew it, whereas those who were not aware were ignorant of it."

As far as the preventive approach in health, Prophet Muhammad (pbuh) said:

"An ounce of prevention is better than a ton of treatment."

Hence, healing medicine is an art and a science. It is done through prevention (prophylaxis), diagnosis, treatment, and cure. In so doing, the individual may prolong his happy life and reduce the degree and the rate of occurrence of illness. Islam encompasses all these approaches so that a person may stay healthy, happy and strong.

Seeking remedy in Islamic jurisprudence maybe obligatory, encouraged, facultative, makruh or forbidden (Albar, 2007). It is obligatory in life saving situations; it is haram if it contains amulets, sorcery, medication made of any intoxicant, using of porcine material, dead carcass even if it is halal (Quran 2: 168, 5:4, 5:93 and 2:219).

### 3. GOOD MANUFACTURING PROCESS (GMP) OF VACCINE

World Health Organization (WHO) defined GMP as part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP covers all aspects of manufacturing steps, suitable premises, storage and transport, qualified and trained production and quality control personnel, adequate laboratory facilities, approved written procedures and instructions, records to show all steps of defined procedures have been taken, full traceability of a product through batch records and distribution records and systems for recall and investigation of complaints (Bennet and Cole, 2003). The guiding principle of GMP is that quality is built into a product, and not just tested. Therefore, the assurance is that the product not only meets the final specifications, but that it has been made by the same procedures under the same conditions each and every time it is made. Validation is the part of GMP that ensures that facility systems, equipment, processes, and test procedures are in control and therefore consistently produce quality product (PDA, 2007). Manufacturing viral vaccine today is a complicated process even after the difficult task of creating a potential vaccine in the laboratory. The effort to manufacture a small quantity potential vaccine in the laboratory to large production scale is way too complex, and simple laboratory procedures will not suffice. The development of a vaccine, its characterization, testing and validation is a great task looking at the candidate that is to be used in the vaccine development. Non-clinical assessment plays an essential part in the overall development of vaccine candidates. Currently, there is limited guidance on non-clinical assessment programs for these products. In the guidance document, the general principles of non-clinical assessment of vaccines are discussed, with particular attention being given to the regulatory expectations for new and novel diseases. Non-clinical studies are aimed to define *in vitro* and *in vivo* characteristics of candidate vaccines including safety and immunogenic evaluations. Non-clinical studies in animals are valuable tools to identify possible risks to the vaccines and help to plan for protocols for subsequent clinical studies in human subjects. Preclinical testing is a prerequisite to move a candidate vaccine from laboratory to clinic which includes all aspects of testing, product characterization, proof of immunogenic studies and safety testing in animals conducted before introducing it into humans. Some of the important elements for the design and the interpretation of nonclinical testing of vaccines include the biological nature of the starting materials, the manufacturing process and the test methods required to characterize the batches of the products. In Muslim country, another important criterion is to determine the sources of the vaccine itself whether it comes from allowable sources or not. Many vaccines are produced using prokaryotic and eukaryotic microorganisms and slight changes in these organisms may radically affect the vaccine product. Moreover, the quality, safety and potency of these products usually are sensitive to changes in manufacturing conditions. The quality and safety of vaccine preparations cannot be assured solely by end product testing, but depends on the strict control of the manufacturing process following principles of GMP. This includes demonstration of the purity and quality of the starting material in process control testing, testing for process additives, and process intermediates and the development and establishment of lot release tests. The development of appropriate laboratory methods to characterize a vaccine formulation with respect to its components, as well as its safety and potency, is a prerequisite to the clinical use of any new or novel bacterial, viral, or parasite vaccines. At a minimum, candidate vaccines for clinical trials should be prepared under conditions of GMP for clinical trial material. However, full GMP will be required at the later stages of the clinical development. Any change in the manufacturing process during the vaccine

development should be considered carefully to evaluate the impact on the quality, safety, and efficacy of the vaccine and the possible need for additional nonclinical and clinical investigations. As for the production methods, subsequent change in or scale-up following product licensure will necessitate further product characterization to demonstrate comparability with the original lot used to demonstrate safety and efficacy of the product. Potency tests measure biological activity of a vaccine but do not necessarily reflect the mechanism of protection in humans. Potency measurement is often used to verify the consistency of the manufacturing process. The initial concept of potency testing for vaccines was to quantify the biological activity of the vaccine in comparison with reference preparation of known activity, where the antigenic components were not well defined.

The stability evaluation of vaccines is complex, as they are very susceptible to inactivation by environmental factors. Potency as defined in the glossary should be measured as a part of the stability testing, except in those cases where potency testing based on biological activity is not available. Physical and chemical product characterization should be included in the stability evaluation. For a product entering human clinical trials, sufficient data should be generated to support the stability of the product for the duration of the preclinical and clinical trial. In certain cases, accelerated stability data may be used to support preliminary data generated at the normal storage temperature. Stability data to support licensure should be carried out under the proposed storage conditions and should be based on long term real time stability studies. Finally, the stability of standards and reference materials also need to be considered in order to ensure that procedures used to measure relevant parameters are reliably standardized.

#### **4. VALIDATION OF HALAL VACCINES**

Developing and licensing a vaccine is a multi faceted process that takes many years. This is because vaccines are generally given to healthy people, the standards required for ensuring safety are very high. Validation is defined as the establishing of documented evidence which provides a high degree of assurance that a planned process will consistently perform according to the intended specified outcomes including halal. Validation studies are performed for analytical tests, equipment, facility system such as water, steam, air and for processes such as the manufacturing processes, cleaning sterilization, sterile filling and lyophilization. Every step of the process to manufacture a drug product must be shown to perform as intended.

The main purpose of the validation of vaccine and other biopharmaceutical product are to follow the government regulation, to ensure the high quality of the product produced and to reduce the cost of production. The GMP and validation concepts are necessary to ensure quality. Regularly, the validation of a process will lead to quality improvement as well as better consistency. It may also reduce the dependence upon intensive in-process and finished product testing. The WHO developed recommendations and guidelines on the production and control of vaccines and other biological, and these form the basis for ensuring the acceptability of products globally. These documents specify the need for appropriate starting material including seed lot system and cell banks; strict adherence to established protocols; test of purity, potency and safety at specific steps during production; and the keeping of proper records. Upon validation of the vaccines, and the confirmation of the sources, the halal logo should be displayed on the casting of the product to ensure that it can be used by the Muslims without ambiguities. This is also to avoid any arising issues of non-halal vaccine mistakenly used by the Muslim communities.

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